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California Green Chemistry

Prioritization: Quantitative Relative Ranking

July 1, 2011

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Who is GMA?

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Participants

- Dr. Maia Jack, GMA Regulatory and Scientific Affairs
- John Hewitt, GMA West Coast Regional Director
- Dr. Christine Chaisson, The LifeLine Group
- Dr. Christina Cowan-Ellsberry, The LifeLine Group
- Bill Greggs, GMA Consultant

Seminar Purpose and Agenda

Purpose

Share ideas on a quantitative, exposure-based approach to prioritization for health and the environment to meet the mandate of AB 1879.

Agenda

- Introduction and Background
- Health Prioritization
- Environmental Prioritization
- Discussion and Next Steps

Background

Prioritization has been a challenging topic

- Statute: Volume; Potential for Exposure; Sensitive Subpopulations
- Science-based priorities: DTSC scientists, not legislature
- Address highest risks first—make a real difference
- Base priorities on quantitative comparison of hazard and exposure
  - *"…the greatest potential for consumers and environmental receptors to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts."*
  - *"…the greatest potential for public and the environment to be exposed to the Chemical of Concern contained in the product in quantities that can result in adverse public health or environmental impacts."*
- Follow transparent approach: assumptions visible; improve via notice and comment

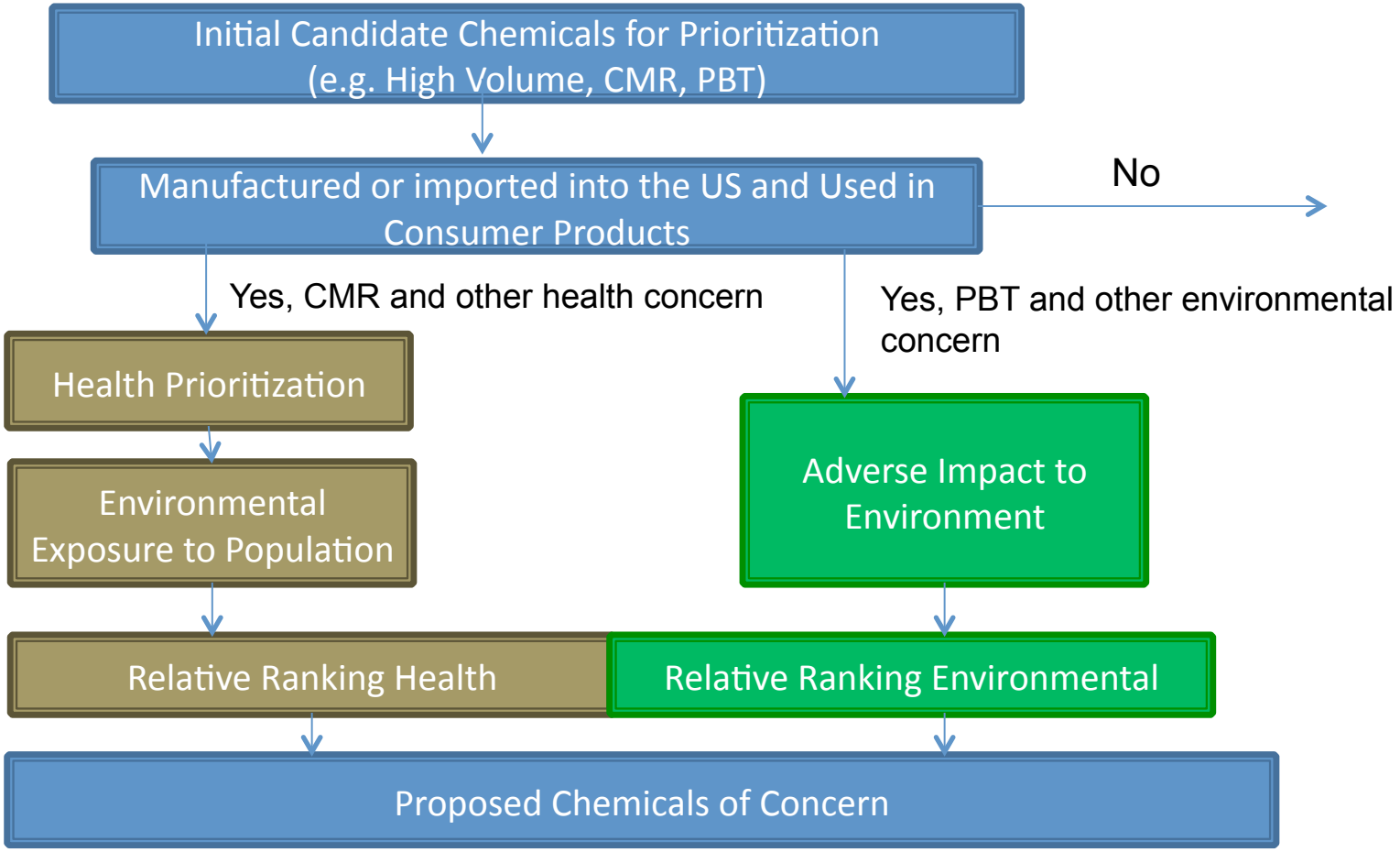
Background

Challenge: “quantitative comparison of hazard-exposure”

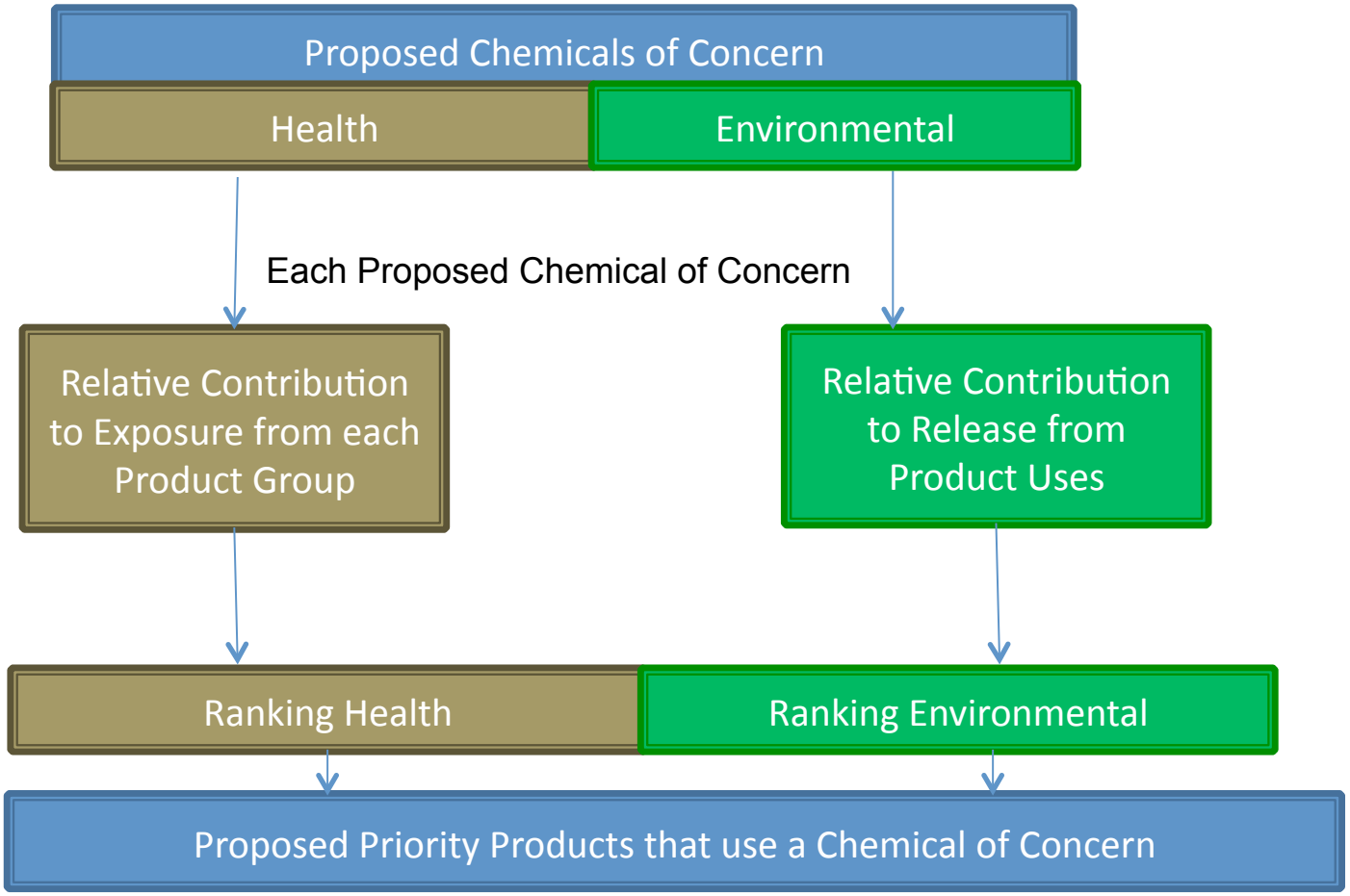
- Hundreds of potential chemicals of concern
- Thousands of potential priority products
- Consider Volume; Potential for Exposure; Sensitive Subpopulations
- Address both health and environment

How would DTSC do that?

Conceptual Framework - Chemical Ranking



Conceptual Framework - Product Ranking



Basis for DTSC Interest

Relative ranking can accomplish the objectives of chemical and product prioritization

- Complies with requirements of the Statute and APA
  - Quantitative comparison of hazard and exposure
  - Considers Volume; Potential for Exposure; Sensitive subpopulations
  - Addresses human and environmental priorities
- Science-based and can be undertaken by DTSC scientists
  - Leverages existing publicly available data
  - Deal with hundreds of potential chemicals of concern; thousands of potential priority products
- Ranked outcome enables addressing the highest impacts first
  - Priorities can be selected to fit within Department resources
- Transparent: Assumptions visible; Improve via notice and comment
- Tested in Canadian prioritization

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Prioritizing Chemicals and Products

Quantitative Relative Ranking

The Process and Techniques

By Christine F. Chaisson, Ph.D.

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Overview

Presentation Chapters

I. Considering the "Regulation for Safer Consumer Products" and basis for prioritization process

II. Principles of Exposure and Hazard Underpinning Prioritization Processes

III. Presentation of Approach for Prioritizing Chemicals and Products

IV. Highlights of Similar Processes in Canada

Chapter I

Considering The "Regulation For Safer Consumer Products" And Basis For Prioritization Process

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Prioritization:
Adverse Public Health Impact

Prioritization based on Adverse Public Health Impact is an important component of the Proposed Regulations

"…the potential for consumers…to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts."

And…

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Prioritization:
Adverse Public Health Impact

"the Department shall seek to identify and ***give priority*** *to those chemicals that pose the* ***greatest threat*** *of adverse public health….are* ***most prevalently distributed in commerce and contained in products used by consumers****, and for which there is the* ***greatest potential for consumers…to be exposed****…"*

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Prioritization of chemicals - Health

So, Objective Seems To Be:

From a large set of candidate chemicals that are used as ingredients for different functions in widely divergent types of products, rank the chemicals as to their probability to cause adverse impacts to different subpopulations who may use those products.

"Adverse impacts" implies a science-based prioritization, utilizing both the potency (hazard) of the chemicals and the exposure to those chemicals via the products under consideration.

Must be a practical and meaningful process

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Prioritization of products

Chemicals are ingredients for functional purposes in products and are needed within ranges of concentrations to accomplish those functions.

The patterns of how people (by age, gender or other classification) use products can be described in exposure scenarios.

A product (or a few products) within a product grouping that are likely to provide the greatest exposure to people (by age, gender, etc) can stand as the Sentinel product(s) in the chemical prioritization assessment. Sentinel products from multiple product groups are considered together in quantitatively ranking relative chemical exposure and adverse impacts.

For each of those chemicals considered to be high priority, the Sentinel products contributing the most to the chemical's exposure and adverse impact potential would be considered to be priority products.

Chapter II

Principles of Exposure and Hazard Underpinning Prioritization Processes

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Prioritization… not Prediction

Prioritization is a relative ranking of groups of chemicals or categories of products based on potential exposure or adverse health impact.

Predictive assessment (including "screening") is chemical-by-chemical or product-by-product estimation of the likely exposure or adverse health impact.

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Prioritization… not Prediction

Prioritization = relative ranking

Underlying approach:

- Products and uses of each chemical are grouped by exposure features
- One (or a few) Sentinel Product(s) from each grouping represents highest plausible exposure scenarios and utilized in ranking calculations.
- Exposure parameter values used in calculations are maximums, not “usual or normative”.
- Generates a list of high to low in relative terms

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Prioritization… not Prediction

Predictive assessment (including "screening")

Exposure and risk assessment methodology employed:

- Single chemical assessments
- All products and uses considered individually or in aggregated assessments
- Values for exposure parameters usually normative (usual values, averages, medians or distributions)
- With limited data, prediction may be crude and/or overestimated (screening approaches).

Prioritization… not Prediction

Advantages of Prioritization Approach

- Initial answers are ranked listings, though based on a quantitative methodology,
- Operates on limited, but decision critical, amounts of data,
- Exposure scenarios for entire groups of products can be efficiently addressed,
- Responsive to requirement for focus on sensitive subpopulations, hazard-based criteria and other legislative requirements.

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Prioritization:
Adverse Public Health Impact

POTENTIAL FOR EXPOSURE is the pivotal parameter for these expressions of priority

Elements of "exposure" for the prioritization include consideration of:

- Probability chemical might be in the products
  - Chemical function/price/manufacturer/country of origin influences this
- Type of Product: Products can be grouped by exposure potential
- Use profiles of products found in households
  - Frequency of use, concentration in product
- Subpopulations…most exposed and most vulnerable

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A Closer Look at the Elements of Exposure

- Probability chemical might be in the products
  - Chemical function/price/manufacturer/country of origin influences this

- Type of Product: Products can be grouped by exposure potential
- Use profiles of products found in households
  - Frequency of use, concentration in product
- Subpopulations…most exposed and most vulnerable

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A Closer Look at the Elements of Exposure

- Probability chemical might be in the products
  - Chemical function/price/manufacturer/country of origin influences this

Function of chemicals in the product
• provides insight into chemicals and concentrations
• provides info for ingredient substitutions

Stabilizers, colorants, polymers, initiators, surfactants, dilutants, etc.

Choice of chemicals for each “product function” influences performance, item price, market availability, and aspects of use of product.

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A Closer Look at the Elements of Exposure

- Probability chemical might be in the products
  - Price/manufacturer/country of origin influences this
- Type of Product: Products can be grouped by exposure potential
- Use profiles of products found in households
  - Frequency of use, concentration in product
- Subpopulations…most exposed and most vulnerable

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A Closer Look at the Elements of Exposure

Categorization defined by exposure potential

- For Illustration Purposes -

Categorizing the TOY STORE !

- Hand held (possible oral)/ light contact
  - Games, blocks, manipulative and craft items
- Hand, face, arm durable contact (likely oral)
  - paints , play dough, face paints, children's makeup
- Whole body contact/ durable/
  - Costumes, hats, face masks, gloves, shoes, stockings, pajamas
- Etc.

FOR ILLUSTRATION— SAME FOR HARDWARE, SALON, ELECTRONICS, OTHER STORES…

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A Closer Look at the Elements of Exposure

- Probability chemical might be in the products
  - Chemical function/price/manufacturer/country of origin influences this
- Type of Product: Products can be grouped by exposure potential

- Use profiles of products found in households
  - Frequency of use, concentration in product

- Subpopulations…most exposed and most vulnerable

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A Closer Look at the Elements of Exposure

Use profiles of products found in households

This is a fundamental element of marketing information for makers of household products. Their business depends on knowing these things regionally, seasonally, socioeconomically, etc.

- Frequency of use – may be seasonally, gender, age specific
- Co-use relationships "If you use lipstick will you use eye liner?"
- Competitive use relationships "liquid vs. powder detergent?"

Product groupings can be made, as with the toy store example, for which probabilities can be assigned for:

- Probability of use
- Co-use with other groupings
- Competitive probabilities with some groupings

Sentinel products can be identified for each grouping

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A Closer Look at the Elements of Exposure

- Probability chemical might be in the products
  - Chemical function/price/manufacturer/country of origin influences this
- Type of Product: Products can be grouped by exposure potential
- Use profiles of products found in households
  - Frequency of use, concentration in product

- Subpopulations…most exposed and most vulnerable

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A Closer Look at the Elements of Exposure

Subpopulations…most exposed and/or most vulnerable

Most exposed - function of interaction with the products and media in which the chemical exists

Most vulnerable – function of biology…a person's proclivity to have an adverse effect from a given exposure to a chemical. Human variability in vulnerability due to age, gender, pregnancy, disease, exposure to other stressors, nutritional status, etc.

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A Closer Look at the Elements of Exposure

Exposure:
Defining Exposure Opportunities via Profiling Use

Use of the products creates opportunity for exposures:

- initial exposure to the user
- exposures to others within the personal environment area
- exposure to self and others at later times due to residues created in the personal environment

Disposal of the products may create additional opportunities for exposure via environmental route

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Principles of Prioritization

Principles of Prioritization Guide the Process

- Assessments useful for relative ranking among the chemicals but NOT for prediction of actual exposure for any chemical in the group.

- Assessment based on combined exposure/adverse impact from the sources (products) most likely to present the greatest exposures to the user group (by age/gender)

- Products likely to deliver greatest exposures to the user group are called "Sentinel products" -- will be different for different age/gender groups.

- Approach is conservative not normative…works with the upper bound values within any distribution of values (e.g. if concentration range of chemical in product is 1-5 %, prioritization utilizes the 5 % value)

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The Sentinel Product

- Defined as a product that produces a comparatively high level of exposure:
  - to different subpopulations
  - by one or more routes
- Connect expected consumer use of product to route and degree of exposure
  - Dermal exposure by direct product use and post-use residues
  - Inhalation algorithms accommodate volatile and respirable particles
  - Oral includes hand-to-mouth transfers as well as food.
- Where a substance is used in multiple high exposure potential products then include multiple Sentinel products
- Exposure parameters assumed to be the maximum reasonable value for a range of possible values….not the “most common or representative” value

  [e.g. maximum expected concentration of surfactant in cleaner]

Chapter III

Presentation of Approach for Prioritizing Chemicals and Products

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Prioritization: Starting Point

Candidates for Prioritization :

- Production Volumes and use in consumer products
- Hazard properties and other information indicating potential for significant impacts on public health or environment, especially sensitive subpopulations.

This will likely narrow the chemical candidates to 100 to < 1000.

From these candidates, proposed “Chemicals of Concern” and “Priority Products” must be drawn, using exposure-based prioritization methods.

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Prioritization: The Process - Health

The chemicals undergo a prioritization task where they are ranked as to their potential to cause adverse impacts, using an exposure-based assessment system.

The approach entails:

1. Identifying the functional uses of the chemical and consumer products in which it occurs,
2. Grouping products by exposure features and from the groupings, selecting Sentinel Products on which the prioritization assessment is based,
3. Considering how people use the Sentinel products, human exposure scenarios are derived for each product group and exposure/adverse impacts across groups calculated in a relative-ranking model which
   a) Displays the relative ranking of adverse impact by chemical
   b) Displays the relative contributions to total impact made by product groups.

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Prioritization: Necessary Information

Three types of information needed for prioritization based on potential for public health impacts.

- Chemical Specific Information
- Product Specific Information
- People Specific Information

Information = data, surrogate data, derivations, default values, assumptions

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Necessary Information: Chemical Specific

- Chemical Specific Information
  - Hazard/toxicology information
    - Toxicological Endpoints that meet the standard of significant public health effects
    - Requires experimentally defined NOEL or *de minimus* level for significant toxicological endpoints.
    - Requires public policy decisions re: endpoints and use of surrogate data or derived information (SAR)
  - Exposure related information
    - Lipophilicity, size, vapor pressure, reactivity, etc.
    - Functionality because of its chemical properties
    - Usually readily publicly available

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Necessary Information: Product Specific

Product Specific Information

- Ingredients and their functionality in products
  - Surfactants, solvents, colorants, stabilizer, etc.
  - Ranges of concentrations for functional ingredients
- Use scenarios—how products are used by different people during different seasons and conditions
- Product co-uses and competitive uses
- Information applicable to many chemicals, so when product use profiles are constructed, much of the information is reusable across many chemicals
- Much of the information is publicly available

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Necessary Information: People Specific

People Specific Information

- Morphometrics and physiological parameters (height/weight, breathing rates, etc)
- Age dependent activity profiles
- Demographic, econometric and ethnic activity-related influences (special subgroups)
- Once information is developed, useful for all subsequent analyses
- Independent of chemical
- Can be constructed or customized from available scenarios developed by government agencies

Practical Considerations of the Approach

Availability of Department resources is a stated factor in prioritization

Creating a Process that is both responsive to the legislative intent AND practical in terms of Department resources:

- Draw on experience of previous related efforts nationally, internationally
- Focus on critical points of the process for quality control (expert oversight)
- Utilize, as possible, existing tools, information sources, expertise
- Utilize notice and comment to improve outcomes

Practical Considerations of the Approach

"Proof Of Concept" Trial

Health Canada Commissioned The LifeLine Group 2005/2006

Part of the initiation of the process for prioritization of chemicals under Canada Environmental Protection Act

Task: For >200 chemicals, identify uses, concentrations in product categories, choose Sentinel products and key exposure elements for prioritization

Practical Considerations of the Approach

Lessons Learned:

1. Information gathering, initial use profiling and choice of Sentinel product(s) requires 4 hours or less per chemical for most chemicals.
2. Exposure scenarios for products are “reusable” across many chemicals, so efficiency increases as the process continues.
3. Prioritization models and underlying knowledgebases and algorithms exist but need to be upgraded and peer reviewed.
4. Needed information is increasingly available, spurred by other regulatory and private transparency initiatives, in organized public and commercial databases

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Prioritization: A View of the Process - Health

Initial Candidate Chemicals for Prioritization
(example criteria)
CMR's and PBT's
High Production Volume Chemicals
Chemicals found in biomonitoring or in children's products
Chemicals of interest identified by Department or other authority
Ingredients in Consumer Products

Define Uses, Products for Each Chemical
Set up Search Criteria, parameter lists, train personnel
Use Public and Industry-Provided Info
Conduct Info Searches (4 hrs/chem)

Chemicals Needing more info

Chem Uses and Products

Choose Sentinel Products
For each chemical by age/subpop
With key parameters for the exposure assessment in prioritization process

Relative Ranking via prioritization model using standardized parameters and defaults

PROPOSED CHEMICALS OF CONCERN

PROPOSED PRIORITY PRODUCTS USING CoC

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Step 1: Candidate Chemicals

From the initial listing of chemicals in commerce, initial candidate chemicals can be identified to undergo the prioritization process…

For Example:

- Production volume;
- CMR's and PBT's;
- Chemicals that are ingredients in consumer products;
- Other information indicating the potential for significant impacts on public health, especially sensitive subpopulations;
- Chemicals of interest to the Department or other CA agencies.

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Step 2: Defining the Uses and Products

Defining the Uses and Products
Using Publicly Available Information

- Uses in products driven by functionality of the chemical (surfactant, colorant, stabilizer, solvent, scent etc)
- Functionality driven by basic physical/chemical properties and this informs initial searches for use profiles
- Publicly available information usually provides good initial listing of uses and potential products for consideration.
- The product uses are grouped by their exposure features

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Examples of public info

How are Chemicals Used in Products? Chemical Use Info and Tox Reviews

- Chemical sales literature and safety information (online)
- Government chemical and product reviews such as http://www.nicnas.gov.au/publications/information_sheets/existing_chemical_information_sheets

Characteristics of the chemical, sources, related information

- US Nat'l. Ctr for Biotechnology http://www.ncbi.nlm.nih.gov
- Forms, sources, links to other info sites http://www.chemindustry.com

Concentrations in products, functions in products and use scenarios/profiles

- Government (example: EPA IUR; Household Products Database http://hpd.nlm.nih.gov)
- European evaluations under REACh. Over 4,000 dossiers available now, including high hazard chemicals; expected to double by 2013
- The Cosmetic, Toiletry, and Fragrance Association (2006) International Cosmetic Ingredient Dictionary and Handbook, Washington DC, Ed Wenninger JA McEwan GN
- American Cleaning Institute (2010) Consumer Product Ingredient Safety, 2nd Edition, Washington, DC

Exposure factors for assessment calculations:

- US EPA Exposure Factors Handbook
- LifeLine™ compendia of activity profiles and dietary profiles

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Defining Products/Uses

Listing of Products/Product Groups: example

Level of Detail?? Detail needed to the degree that it influences ingredient use profiles: Who uses it? How frequently? How much? When? How?

Product Grouping-Personal Care	Exposure Parameters [Examples]
deodorant spray, roll-on-stick, pump	→ Dermal/Inhalation Exposure Exposure to self only or bystanders
soaps and cleaners shaving cream body washes shampoos	→ Co-use or competitive use probabilities Ingredient issues: aromatics/colorants/etc
toothpaste children's regular de-sensitizing	→ Concentration of ingredients in product types: this will drive selection of assessment values and Sentinel products. Example: concentration of surfactants in children's toothpaste may be 5X that of other toothpastes. Reason…making bubbles!

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Step 3: Selecting The Sentinel Products

- Defined as a product that produces a comparatively high level of exposure:
  - to different subpopulations
  - by one or more routes
- Product selection based on general principles of exposure
  - Connect expected consumer use of product to route and degree of exposure
  - Higher concentrations and larger amounts of a substance increase the potential for higher dose
  - Exposure parameters assumed to be the maximum reasonable value for a range of possible values….not the “most common or representative” value
- Where a substance is used in multiple high exposure potential products then include multiple Sentinel products

Choosing Sentinel Products or "Important Use Scenarios"

Criteria Matrix for Choosing Sentinel Products

This is a critical step in the prioritization process. Clear decision criteria should be developed to guide a disciplined, consistent prioritization process.

- **Criteria may be reflect regulatory mandate for:**
  - Degree of conservativism
  - Completeness
  - Acceptable uncertainty
- **Experience and resources**

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Selection Criteria for Sentinel Products

Underlying Premises:

1. Exposure is NOT proportionately distributed across the population
2. Exposure defined by duration, frequency, route as well as magnitude
3. Product use varies among different subpopulations
4. Product use varies from period to period for any given individual
5. A structured approach is needed for selecting Sentinel products and choosing values for exposure parameters so that consistency of approach is assured.

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Choosing Sentinel Products or "Important Use Scenarios"

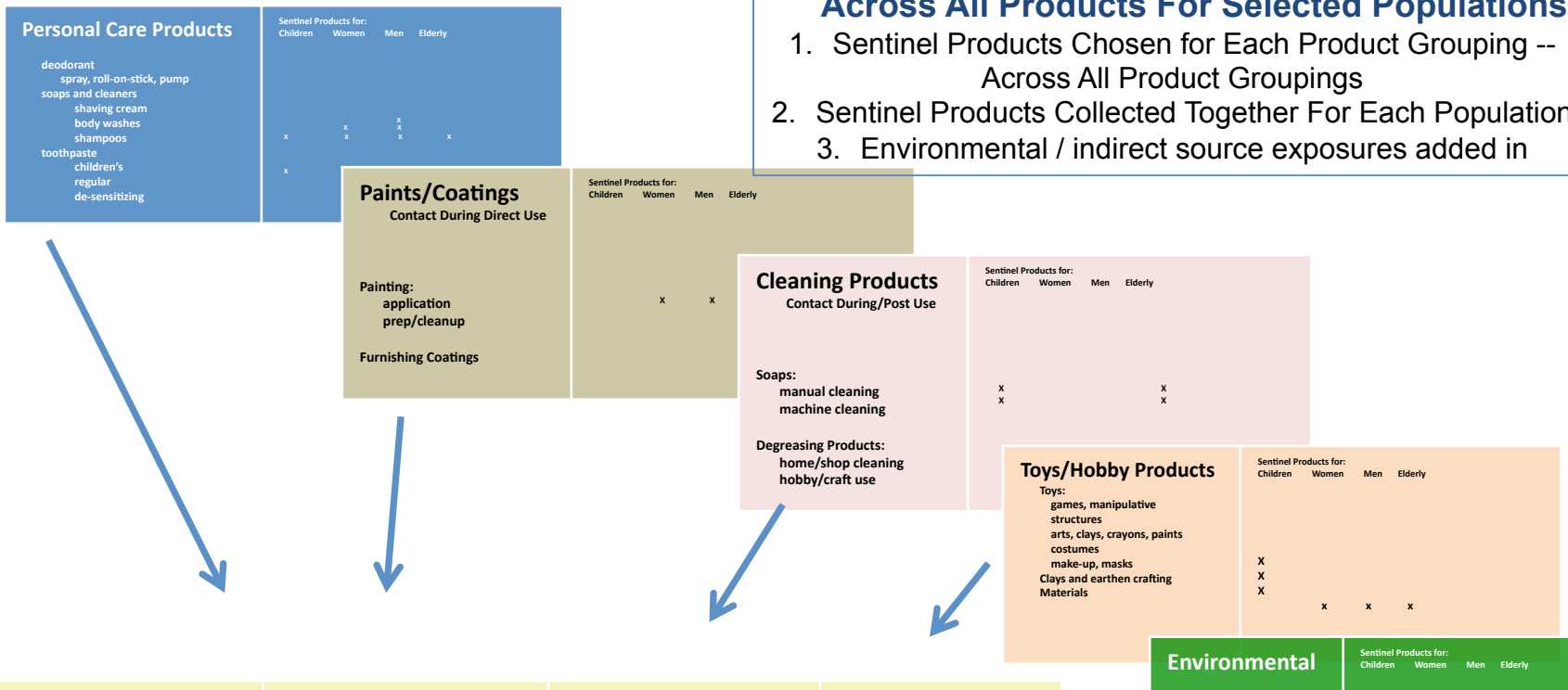
Example: Surfactant A

Product Groupings	Sentinel Products for: Children	Women	Men	Elderly
Personal Care Products	x	x	x	x
Cleaning Products		x		
Toy/Hobby Products	x			
Paints/Coatings			x	
Pesticide Products	x			x

Example: Surfactant A

Setting Up Highest Personal Exposure Scenarios Across All Products For Selected Populations

1. Sentinel Products Chosen for Each Product Grouping -- Across All Product Groupings
2. Sentinel Products Collected Together For Each Population
3. Environmental / indirect source exposures added in



Sentinel Products for Children	Sentinel Products for Women	Sentinel Products for Men	Sentinel Products for Elderly
Toys: arts/paints	Hobby clays	Hobby clays	Hobby clays
Toys: costumes	Body Washes	Shaving Cream	Shampoos
Toys: makeup/masks	Shampoos	Body Washes	Soaps/detergents
Shampoos	Interior Paints	Interior Paints	post-use exposure
Toothpaste	Degreasing soaps	Decreasing soaps	
Soaps/detergents	home/shop	home/shop	
post-use exposure	hobby/craft	hobby/craft	
Environmental: all	Environmental: all	Environmental: all	Environmental: all

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Process Yields: Ranked Chemicals - Health

Ranked Chemicals (within candidate chemicals undergoing relative ranking) are identified as those presenting the highest potential for adverse public health impact to any population group by any route.

Prioritization process yields chemicals ranked high to low in terms of potential health impact.

Basis: public health impact based on toxicity potencies - exposure

Process Yields: Ranked Products - Health

Priority Products

identified as:

- Those products making the greatest contributions to total exposure/adverse public health impact for the chemical

These are ranked high to low as a function of age group or gender or other selected subpopulation

Chapter IV

Highlights of Similar Processes in Canada

Experience to Date: Canada

Canada: Prioritization under Canadian Environmental Protection Act (CEPA)

Initial phase (through 2006) of prioritization accomplished through separate parallel programs considering toxicity (hazard potential) and exposure.

No prioritization tools existed at that time. Canada developed hazard ranking approach and prioritization tool based on exposure potential (ComEt) which it used as a proof of concept and employed its principles.

After completing prioritization, Health Canada then initiated chemical-by-chemical screening assessments on highest priority chemicals.

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Experience to Date: Canada

Using a prototype relative ranking tool, ComET, * approximately 200 chemicals were ranked. The following slides illustrate the ranking results, considered by different criteria.

Ranking by Route of Exposure

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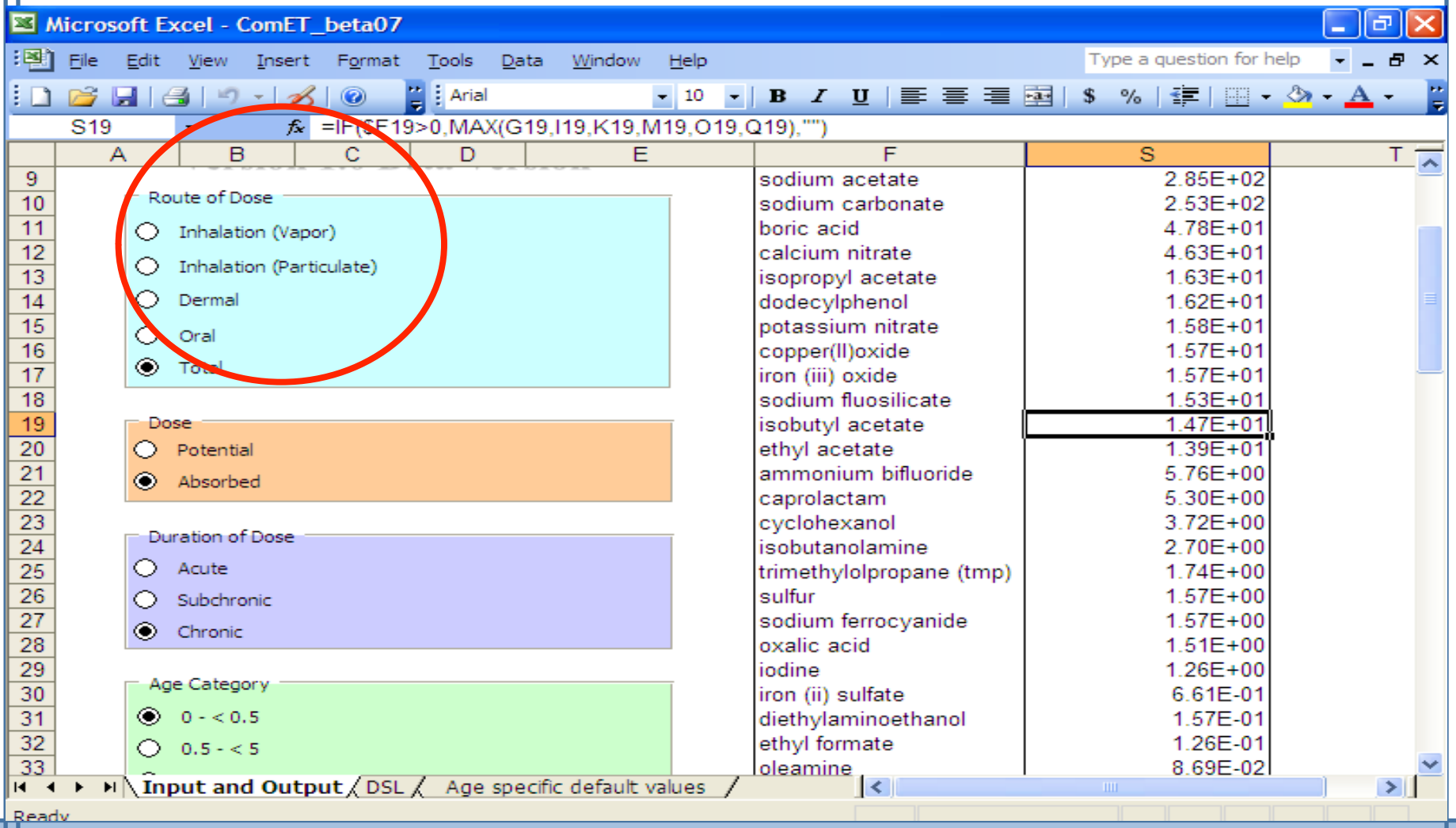

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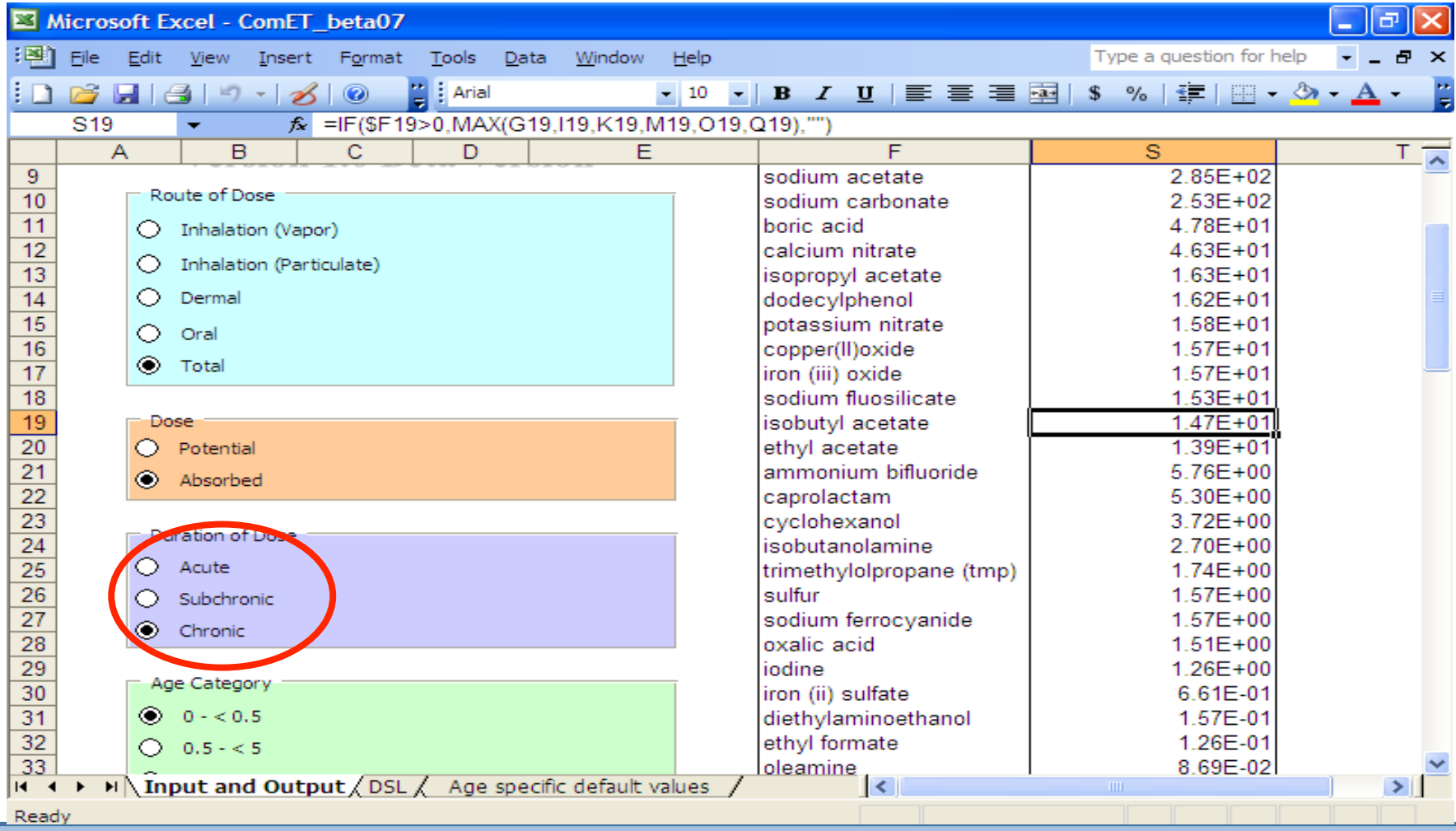
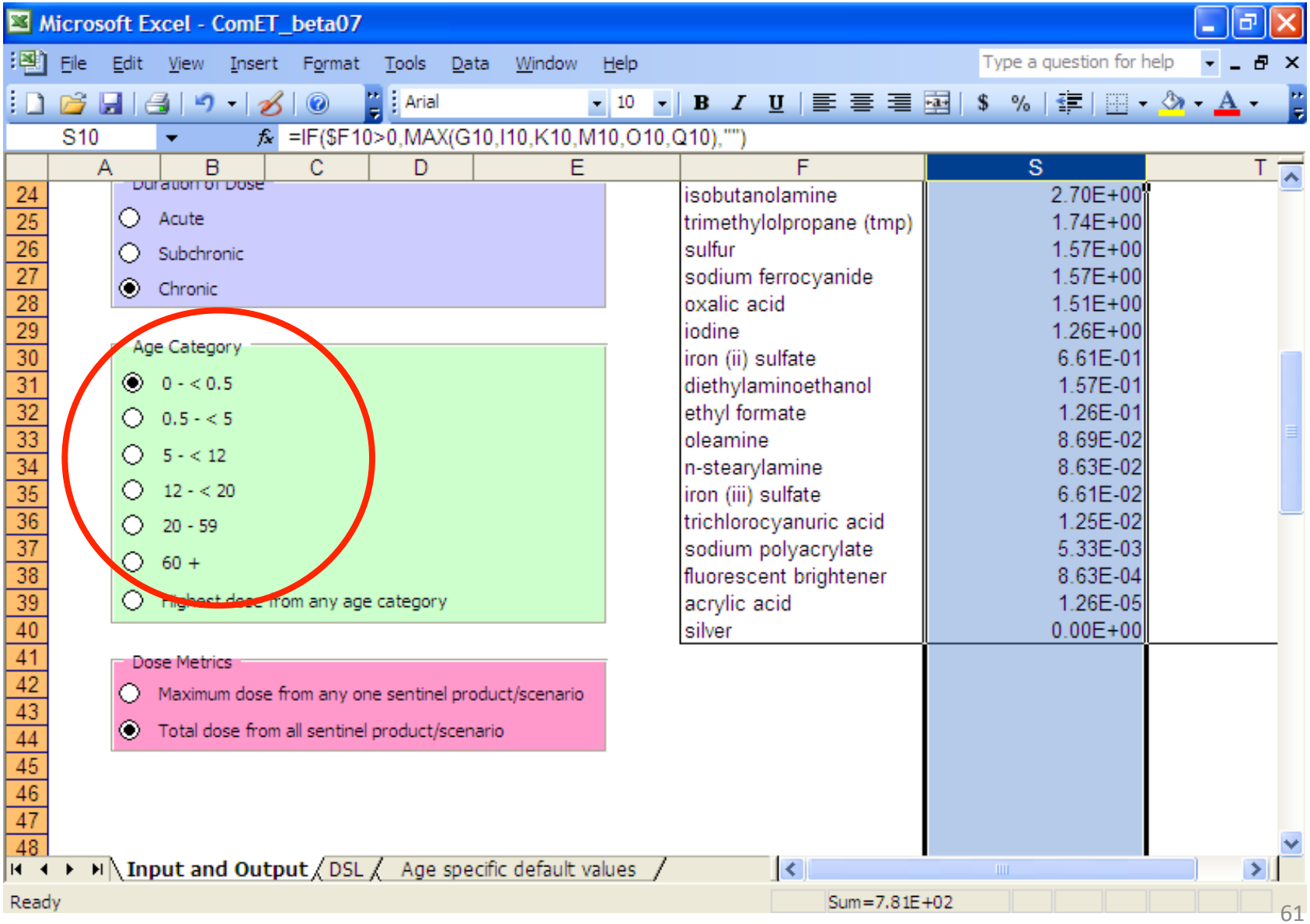
Ranking by Duration of Exposure

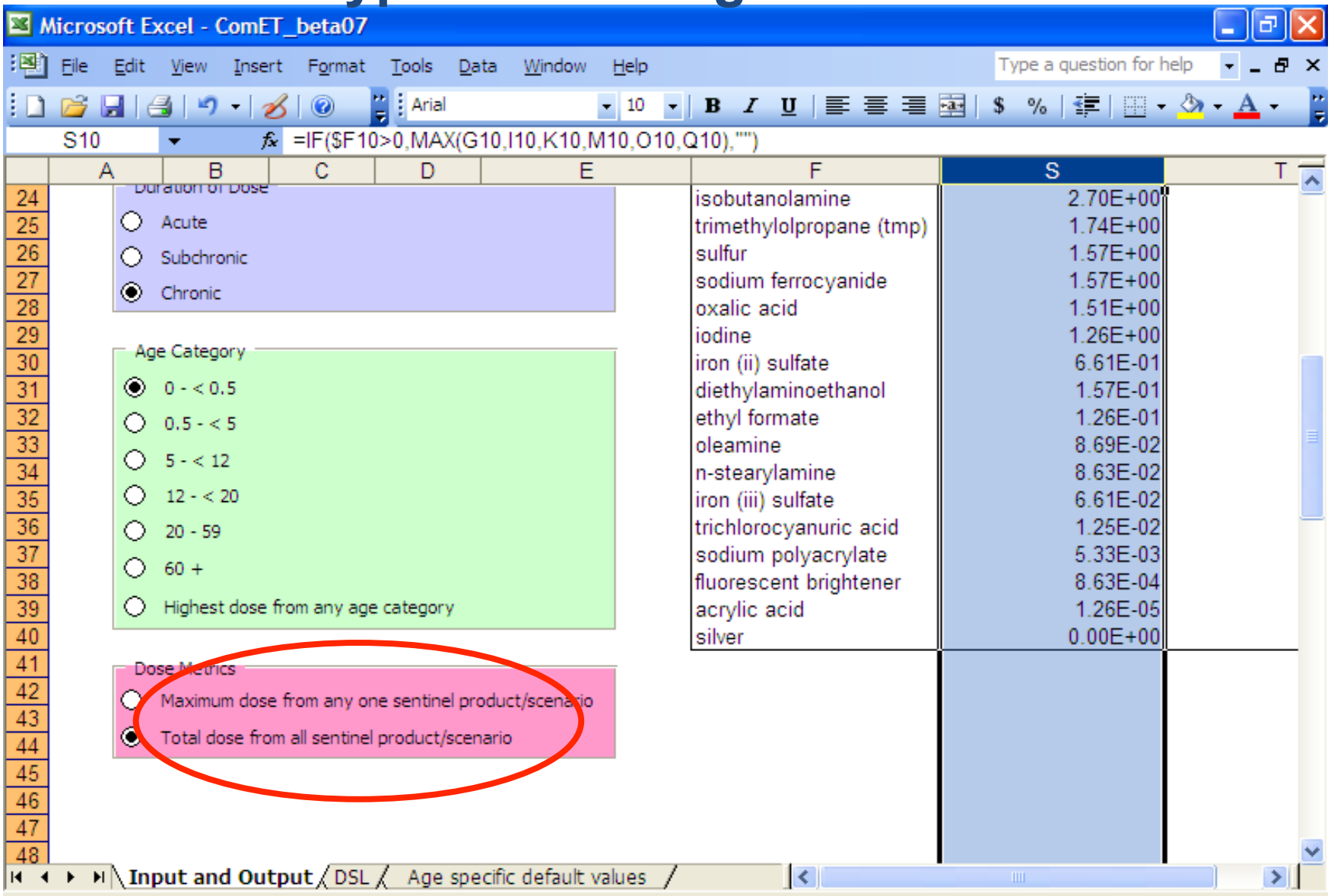


	F	S
9	sodium acetate	2.85E+02
10	sodium carbonate	2.53E+02
11	boric acid	4.78E+01
12	calcium nitrate	4.63E+01
13	isopropyl acetate	1.63E+01
14	dodecylphenol	1.62E+01
15	potassium nitrate	1.58E+01
16	copper(II)oxide	1.57E+01
17	iron (iii) oxide	1.57E+01
18	sodium fluosilicate	1.53E+01
19	isobutyl acetate	1.47E+01
20	ethyl acetate	1.39E+01
21	ammonium bifluoride	5.76E+00
22	caprolactam	5.30E+00
23	cyclohexanol	3.72E+00
24	isobutanolamine	2.70E+00
25	trimethylolpropane (tmp)	1.74E+00
26	sulfur	1.57E+00
27	sodium ferrocyanide	1.57E+00
28	oxalic acid	1.51E+00
29	iodine	1.26E+00
30	iron (ii) sulfate	6.61E-01
31	diethylaminoethanol	1.57E-01
32	ethyl formate	1.26E-01
33	oleamine	8.69E-02

Ranking Exposures within Age Groups



Type of Ranking Exercise



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Experience to Date: Canada

Scientists and regulators initially underestimated the sources and extent of publicly available information available about chemical uses, product characteristics, use profiles, ingredients and other parameters involved with exposure and adverse impact assessment.

Existing private and government databases are informative and are becoming more accessible.

Exposure based prioritization can be accomplished in a time and cost-efficient way, and prioritization (not predictive) models accomplish a conservative approach to relative ranking of chemicals and products.

Assessment tools exist and underlying assumptions, algorithms and default parameters are transparent and available for upgrading/customizing. Easily presentable for peer review and use by all interested parties.

Summary - Health

Advantages of Relative Ranking Approach

- Initial answers are ranked listings, with a disciplined and objective science-based, quantitative methodology; no subjective weighting
- Operates on limited, but decision critical, amounts of data; efficient in time and cost.
- Exposure scenarios for entire groups of products can be efficiently addressed using Sentinel products
- Responsive to requirement for focus on sensitive subpopulations, hazard-based criteria, other requirements.
- Transparent and can be refined with better information

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Environmental Prioritization

Christina Cowan-Ellsberry, Ph.D.

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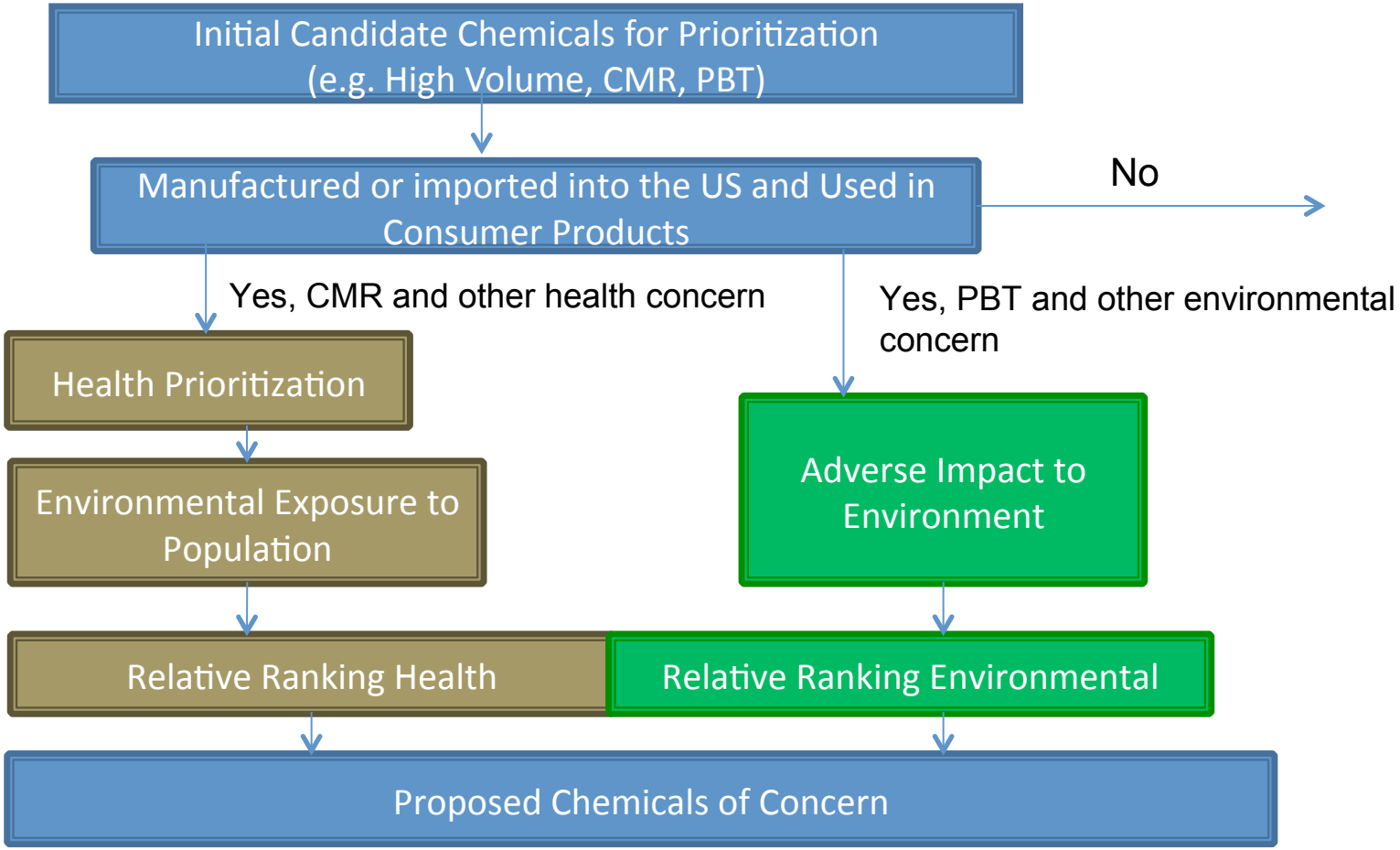
Chemical Ranking - Environmental



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Environmental Prioritization

For Chemical Ranking - Environmental

Adverse Impact on the Environment

- Prioritization based on Screening Level Environmental Exposure and Impact Assessment
    - Using volume of chemical used in California to calculate exposure levels
    - Compared to toxicity values to determine potential for impact on environment and/or organisms of concern

For Chemical Ranking - Health

Environmental Exposure to Population

- Indirect exposure via air, food, water; add to consumer product direct exposure

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Environmental Chemicals of Concern -PBTs

Impact requires presence of chemical in environment plus ability to get into organism where adverse impact can occur

- **Persistence** is the ability of a chemical to stay unchanged in the environment for a long time.
  - Amount in the environment can gradually build up
  - Even when emissions are reduced or stopped, environmental levels of the chemical will take a long time to decrease
- **Bioaccumulation** is a process by which living organisms, especially those living in water, can collect and concentrate chemicals both directly from the surrounding environment (i.e. bioconcentration) and indirectly from their food.
- **Toxicity** is a measure based on external exposure of the level that results in an adverse effect.

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Environmental Chemicals of Concern -PBTs

Process to identify PBTs for Prioritization

- Compile "Global PBTs" from authoritative body sources
- Compare to EPA's Inventory Update (IUR) to determine which ones are made or imported into US commerce.
- Determine which ones are used in consumer products

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Authoritative Sources - PBTs

Authoritative Sources

- Developed by governmental bodies, e.g., US EPA, EU, UN, Canada
- All based on same internationally accepted criteria in their identification
- Open, deliberative and transparent scientific process in which stakeholders are able to participate
- Widely perceived to be objective, and scientifically based
- Used best science available and typically multiple lines of evidence within a weight-of-evidence approach
- Final characterization and guidance documents are publicly available
- Deliberate, on-going review of the PBT categorization

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Authoritative Sources - PBTs

- **US EPA: TRI and Waste Management PBTs**

  http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm

  http://www.epa.gov/osw/hazard/wastemin/priority.htm

- **Canada: Identified Priority PBTs**

  http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=D031CB30-B31B-D54C-0E46-37E32D526A1F

- **EU: PBT list and Substances of Very High Concern - PBT**

  http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

  http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp

- **Stockholm and LRTAP Conventions**

  http://chm.pops.int/Convention/The%20POPs/tabid/673/language/en-GB/Default.aspx

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PBTs in Consumer Products

- Use EPA IUR identified chemicals in US commerce
  - http://www.epa.gov/iur/tools/data/index.html
  - Expected to be updated in 2011
- Determine use in consumer products
  - Detailed discussion in Health Prioritization presentation

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Chemical Ranking - Environmental

- **Screening level environmental exposure based on levels in California**
  - Based on volume of chemical used in California (assume all is released to the environment)
  - Not particular location but average in California in that media - surface water and soil
  - Exposure to environmental organisms of concern
- **Screening Level Impact Assessment**
  - Compare these environmental exposure levels to predicted or measured environmental toxicity data for the chemical
    - E.g., Surface water concentration/Aquatic toxicity value
  - Compare exposure of organisms of concern to toxicity values

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Volume in California

- Use current US EPA IUR volume
  - http://cfpub.epa.gov/iursearch/index.cfm?err=ch&term=1322981
  - Expected to be updated in 2011
- Calculate the California volume by using percent of US population in California
  - ~12% based on 2009 Census information

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Adverse Effect Data

- Sources:
  - ECOTOX database:
    - http://cfpub.epa.gov/ecotox/
  - REACH registrations:
    - http://apps.echa.europa.eu/registered/registered-sub.aspx
  - OECD HPV program and related information:
    - http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
  - US HPV:
    - http://www.epa.gov/hpvis/
  - US EPA chemical data access tool
    - http://java.epa.gov/oppt_chemical_search/
  - QSARs: EPISuite and others

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Screening Environmental Exposure Tool(s)

- Considerations
  - Predict exposure levels in California environment
  - Based on well-recognized, currently accepted environmental fate and exposure models
    - fully documented, publicly available
    - Are or can be parameterized for California
    - Examples: CalTox, Raidar, EUSES
  - Exposure to environmental organisms of concern

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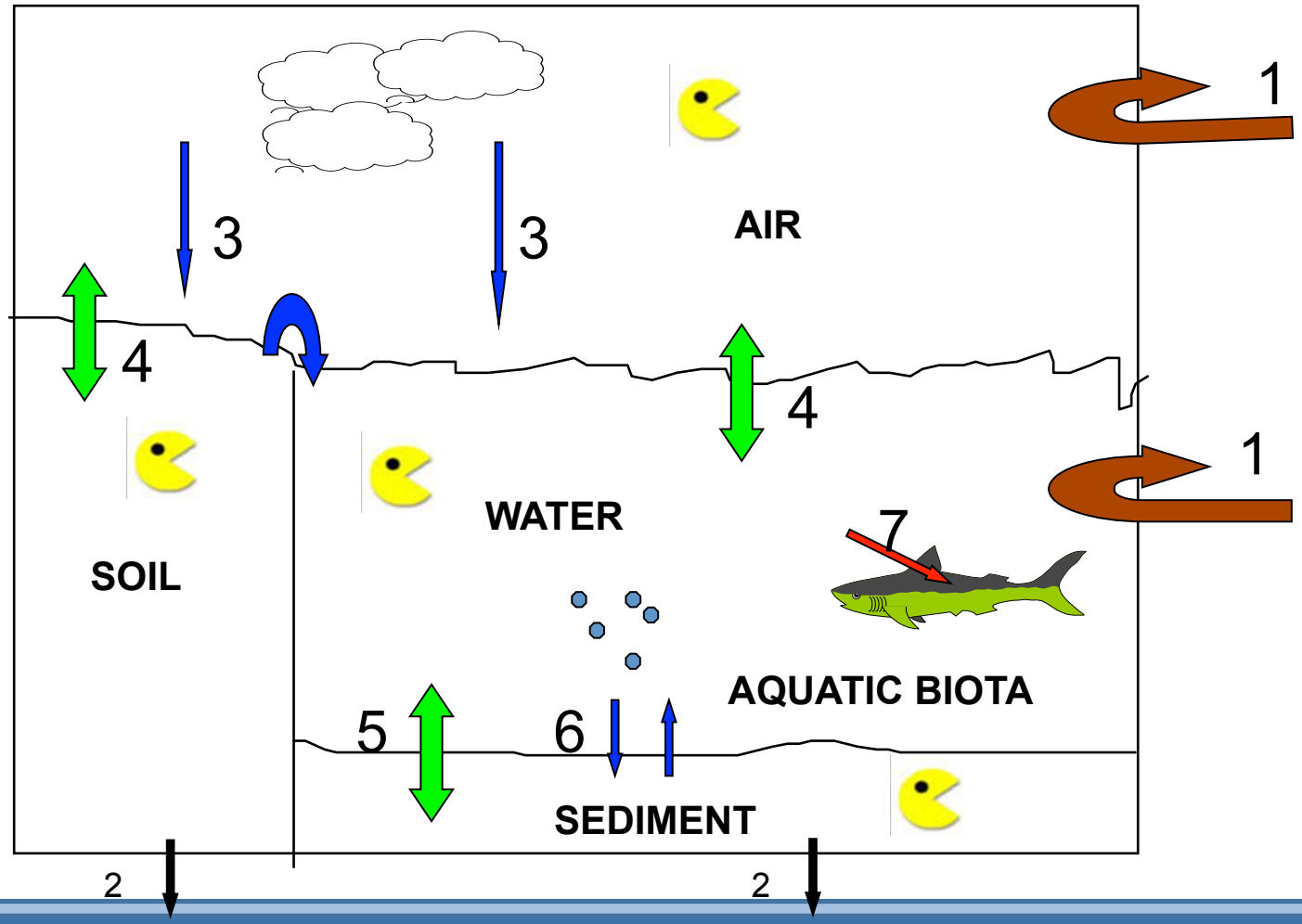
Environmental Fate and Exposure Model



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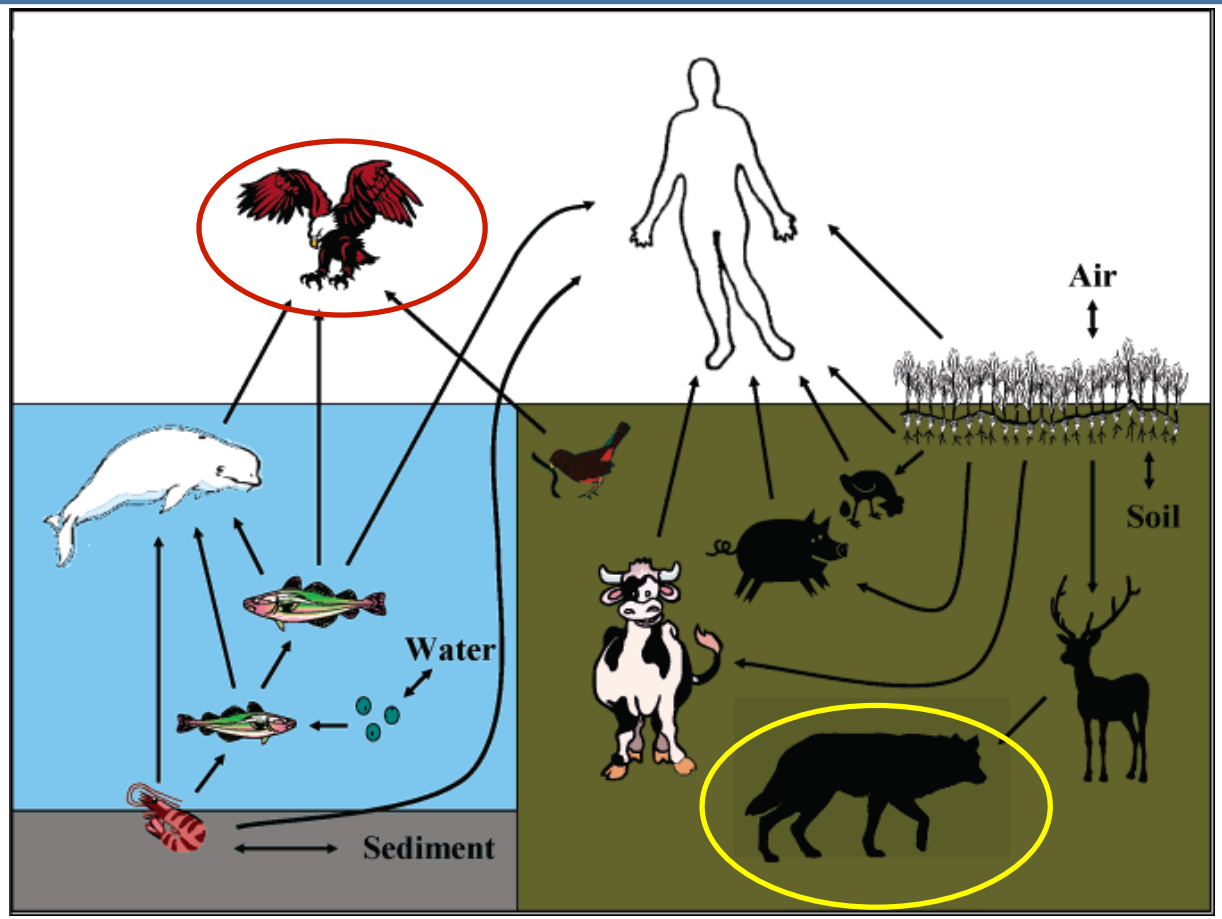
Environmental Exposure Example Tool



RAIDAR Model

Arnot et al. 2006 EST 40:2316-2323

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Environmental Exposure to Population

Candidate Chemicals – Human Health

- CMR or other Health concern
- Initial ranking for Health Prioritization

Environmental Exposure to Population

- Indirect exposure to the Population through the environment needed to complete ranking for prioritization for Human Health

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Environmental Exposure to Population

- Predict the indirect exposure to the population from
  - Air
  - Water – Drinking water
  - Food
- Use Environmental Fate and Exposure model to get primary media exposures (air and water)
- Food exposure by considering chemical flow from environment through to food as well as intake of the various foods by population and/or representative subpopulations

➢ Total exposure ranking by adding estimated environmental exposure to the direct exposure from consumer product use.

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Human Exposure from the Environment - Tool(s)

- Considerations
  - Predict indirect exposure to California population through the environment
    - Air, Drinking water, and food
  - Based on well-recognized, currently accepted modeling approaches, fully documented, publicly available
    - CalTox, Raidar, FHX, etc.
  - Population and/or different representative subpopulation exposures

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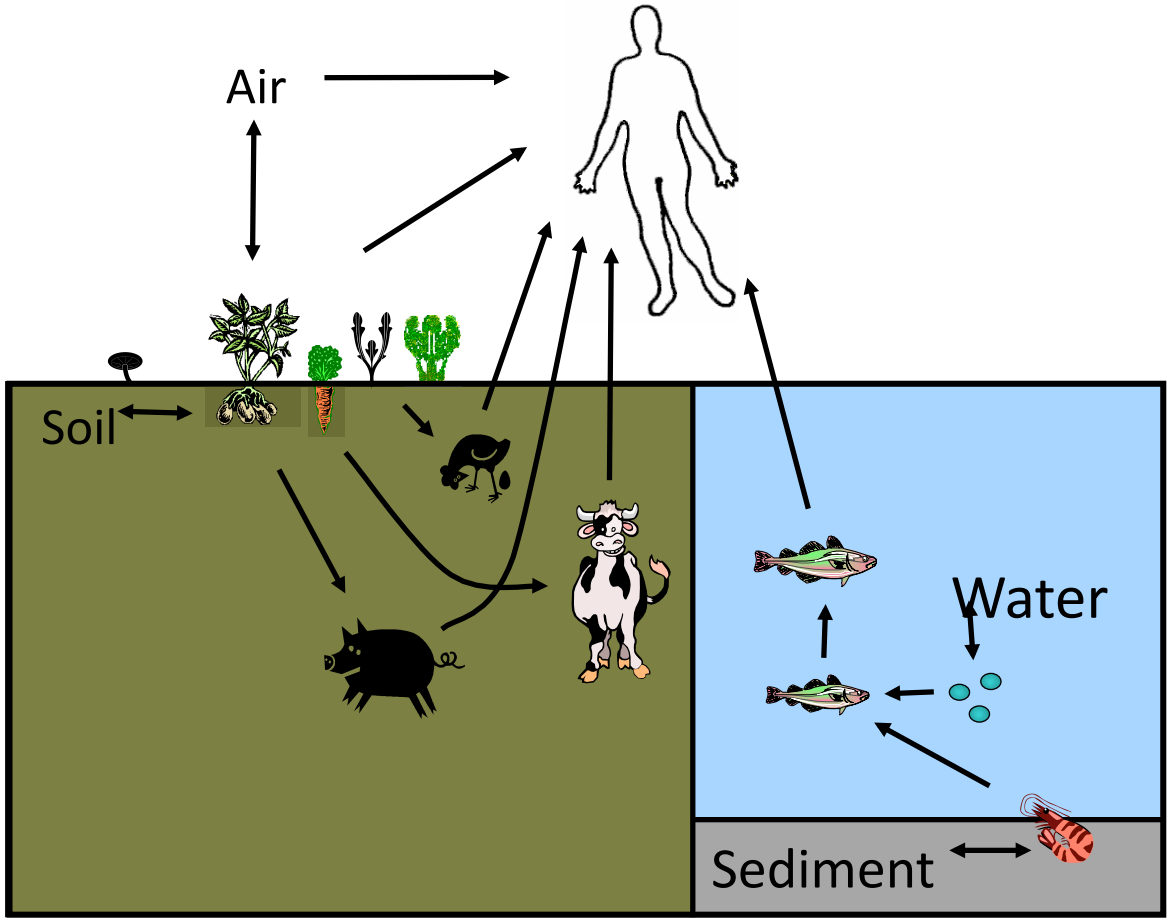
Human Exposure from Environment - Example Tool



RAIDAR and FHX Models

Arnot et al. 2006 EST 40:2316-2323

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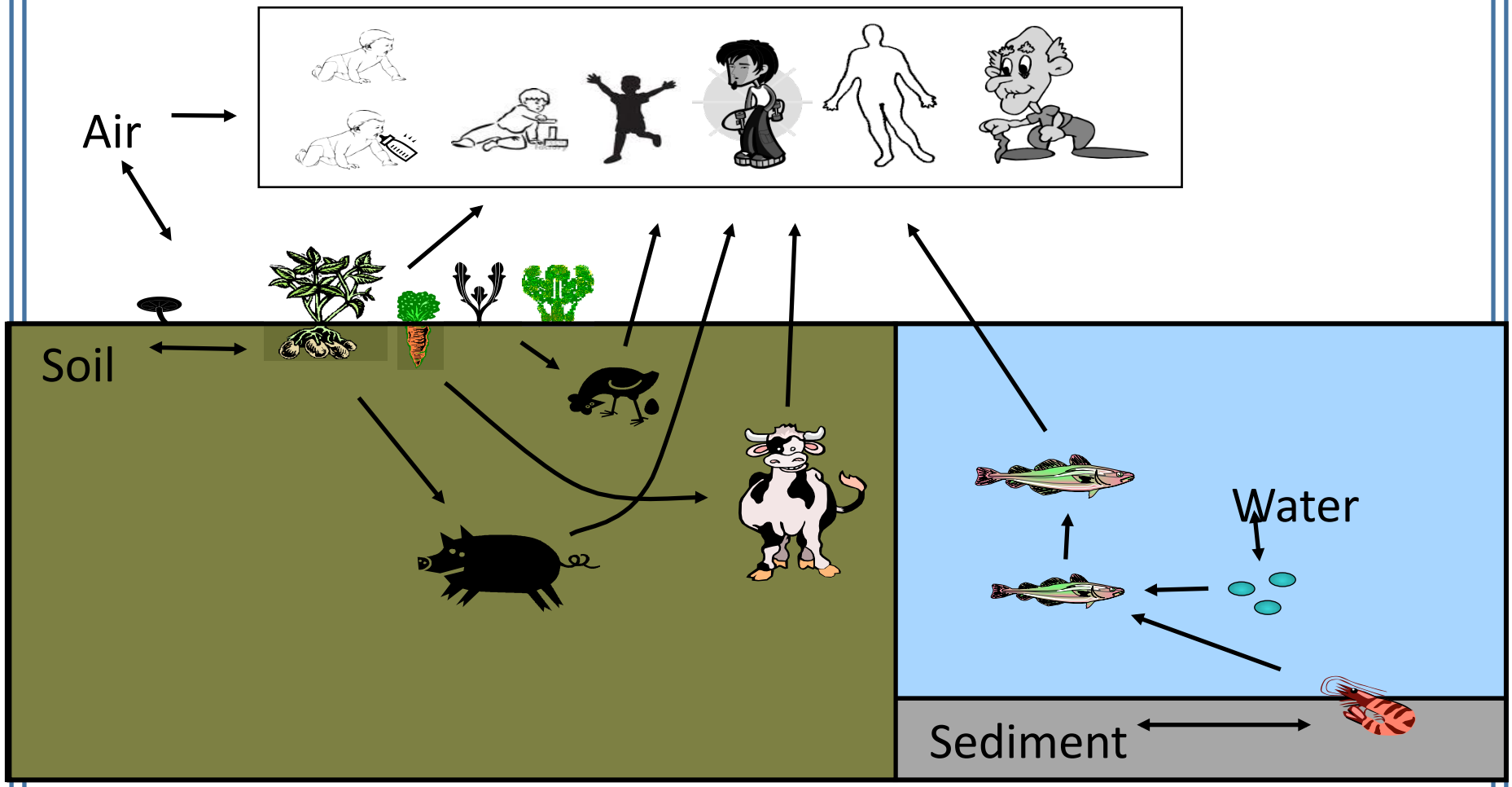
Subpopulations



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Hypothetical Example

Hypothetical Chemicals

- **Chemical A** – high volume chemical used in cleaning products that are disposed down-the-drain
  - Volume in California = 5.5 to 27 million kg/yr
  - Kow = 40, Fish BCF = 2, Half-life in water = 7 days
  - Aquatic Toxicity (LC50) = 10 mg/L
- **Chemical B** – low volume used in personal care products that are disposed down-the-drain
  - Volume in California = 5.5 to 27 thousand kg/yr
  - Kow = 1,380,000, Fish BCF = 16,700, Half-Life in water = 180 days
  - Aquatic Toxicity (LC50) = 0.01 mg/L

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Example Results

Property	Chemical A	Chemical B
Half-life in Surface Water	7 days	180 days
Kow	40	1,380,000
BCF	2	16,700
Aquatic LC50	10 mg/L	0.01 mg/L
Volume in California	5.5 to 27 million Kg/yr	5.5 to 27 thousand Kg/yr
Surface Water Concentration	**3.6E-8 mg/l**	**3.0E-6 mg/L**
Impact Ratio	**3.6E-9**	**3.0E-4**
Env. Exposure to Population	**1E-8 gm/yr**	**0.19 gm/yr**

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Example Ranking

Ranking Environmental:

- Chemical B would be ranked as higher priority over Chemical A
  - PBT, higher Impact Ratio for Environmental Ranking
- Product ranking considers the relative proportion of chemical volume used in different product types and what fraction is released to the environment
  - A product using Chemical B that releases more to the environment would be ranked as higher priority over products that release less

Ranking Human Health:

- Add the estimated indirect Environmental Exposure to the Population to exposure estimate from Consumer Products

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Summary - Environment

- **Candidate Chemicals – Environmental**
  - **PBTs**
- **Ranking for Prioritization**
  - **Adverse Impact on the Environment For Environmental Prioritization**
    - Chemical: Environmental Impact Assessment using California volume of chemical and appropriate toxicity value
    - Product: Relative contribution to chemical release from product uses
  - **Environmental Exposure to Population For Human Health Prioritization**
    - Environmental exposure to Population or representative Subpopulations combined with consumer product exposure to provide overall Health ranking

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Prioritization:
Quantitative Relative Ranking

Summary

www.gmaonline.org

Advantages to Relative Ranking

The rankings are quantitative, conservative

Address both human health and environment

Responsive to sensitive sub-population requirement

Credible, practical, transparent, objective

Potential Criticisms of this Approach

Requires department product safety capability

- DTSC has not been a product safety agency
- Statutory mandate requires new knowledge/skills/ resources

Appears to have significant data requirements

- Experience to the contrary
- Much info readily available; can be improved with comment

Qualitative ranking is simpler

- Qualitative approaches are subjective and difficult to defend scientifically

Conclusion

Relative ranking can accomplish the objectives of chemical and product prioritization

- Complies with requirements of the Statute and APA
  - Quantitative comparison of hazard and exposure
  - Considers Volume; Potential for Exposure; Sensitive subpopulations
  - Addresses human and environmental priorities
- Science-based and can be undertaken by DTSC scientists
  - Leverages existing publicly available data
  - Deal with hundreds of potential chemicals of concern; thousands of potential priority products
- Ranked outcome enables addressing the highest impacts first
  - Priorities can be selected to fit within Department resources
- Transparent: Assumptions visible; Improve via notice and comment
- Tested in Canadian prioritization

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Thank you !

Maia Jack, Ph.D.
mjack@gmaonline.org
(202) 639-5922